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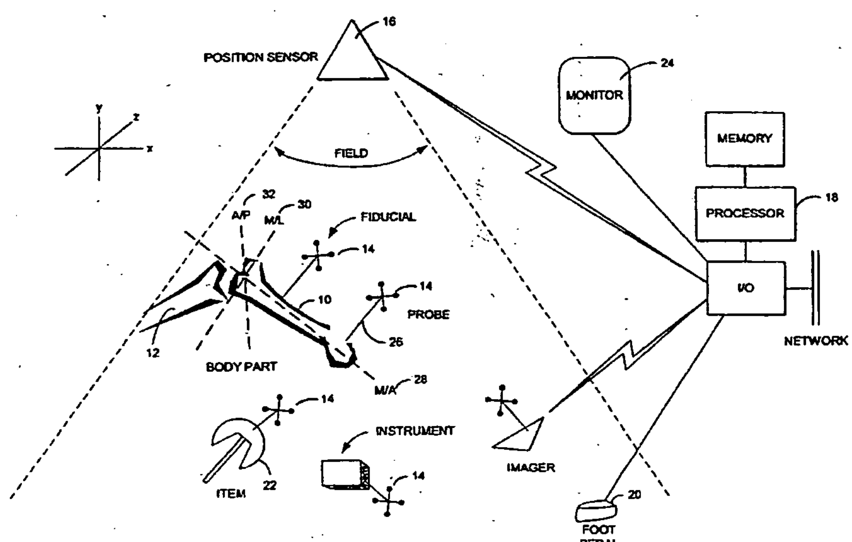
(54) Title: SURGICAL NAVIGATION SYSTEMS AND PROCESSES FOR HIGH TIBIAL OSTEOTOMY



(57) Abstract: Systems and processes for tracking anatomy, instrumentation, and references, and rendering images and data related to them in connection with surgical operations, particularly high tibial osteotomy ("HTO"). These systems and processes are accomplished by using a computer to intraoperatively obtain images of body parts and to register, navigate, and track surgical instruments.

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SURGICAL NAVIGATION SYSTEMS AND PROCESSES FOR HIGH TIBIAL OSTEOTOMY

RELATED APPLICATION DATA

This document claims the benefit of USSN 60/271818, filed February 27, 2001 entitled "Image Guided System for Arthroplasty" and USSN 60/355,899, filed February 11, 2002 entitled "Surgical Navigation Systems and Processes," which documents are incorporated herein by this reference.

FIELD OF THE INVENTION

This invention generally relates to use in certain osteotomy surgery, of systems and processes for tracking anatomy, implements, instrumentation, trial implants, implant components and virtual constructs or references, and rendering images and data related to them in connection with orthopedic, surgical and other operations. Anatomical structures and such itemsmay be attached to or otherwise associated with fiducial functionality, and constructs registered in position using fiducial functionality, whose position and orientation can be sensed and tracked by systems and according to processes of the present invention in three dimensions. Such structures, items and constructs can be rendered onscreen properly positioned and oriented relative to each other using associated image files, data files, image input, or other sensory input, based on the tracking. Such systems and processes, among other things, allow surgeons to navigate and perform surgical operations using images that reveal interior portions of the body combined with computer generated or transmitted images that show surgical implements, instruments, trials, implants, and other devices located and oriented properly relative to the body part. Such systems and processes allow, among other things, more accurate and effective resection of bone, placement and assessment of trial implants and joint performance, and placement and assessment of performance of actual implants and joint performance.

BACKGROUND

In unicompartmental arthritis of the knee, high tibial osteotomy ("HTO") is a treatment of choice. HTO is a common treatment for tibia vara (bow legs). An osteotomy is a surgical procedure to realign a bone in order to change the biomechanics of a joint, especially to change the force transmission through a joint. HTO is a corrective surgical procedure in which the upper part of the tibia is resected so that the lower limb can be realigned. The purpose of HTO is to realign the deformed tibial plateau to shift the load bearing into the unaffected compartment of the knee.

There are three types of HTO: closing wedge, open wedge, and cylindrical barrel. The closing wedge HTO is the most common procedure and it involves realignment of the bone by removal of a lateral wedge of bone from the proximal tibia. The wedge is first planned on a frontalplane standing X-ray by drawing a wedge of the desired correction angle, where the wedge's upper plane is parallel to the tibial plateau and the lower plane is above the tibial tubercle. Ideally, the wedge will produce a hinge of cortical bone approximately 2-5 mm in thickness.

Upon surgical exposure of the proximal tibia, the correction is mapped to the bones of the patient with a ruler or a jig system. The surgery is then performed either free-hand or with the assistance of Kirschner wires (K-wires) as cutting guides. Intraoperative fluroscopic X-ray is often employed for verification before and during the procedure.

Unlike total knee arthroplasty ("TKA"), HTO preserves the joint's original cartilaginous surfaces and corrects the fundamental mechanical problem of the knee. This advantage is especially important to young active patients because TKA has a greater probability of earlier failure in active patients.

However, problems remain in HTO performance. A major difficulty with HTO is that the outcome is sometimes not acceptably predictable because it is difficult for a surgeon to attain the desired correction angle. Current instrumentation cannot accurately produce the desired resection from pre operative plans. On average, the margin of error is reported between 6° and

14°. Technical difficulties also arise from the use of fluoroscopy, such as image-intensifier nonlinearities and distortions that compromise accuracy, and parallax errors that can provide misleading angular and positional guidance. Additionally, the use of continual fluoroscopic imaging is sometimes required thus exposing the surgeon and assistants to radiation.

Several providers have developed and marketed improved cutting jigs that have improved the accuracy of the resection in HTO. However, extensive fluoroscopic time is still needed for the positioning of the jigs. Inaccurate pin placement can also affect the accuracy of the alignment of the resection, thus increasing shear stresses across the osteotomy. Other providers have developed various forms of imaging systems for use in surgery. Many are based on CT scans and/or MRI data or on digitized points on the anatomy. Other systems align preoperative CT scans, MRIs or other images with intraoperative patient positions. A preoperative planning system allows the surgeon to select reference points and to determine the final implant position. Intraoperatively, the system calibrates the patient position to that preoperative plan, such as using a "point cloud" technique, and can use a robot to make femoral and tibial preparations.

Accordingly, there is a continuing need for an intraoperative planning system and process for performing HTO's with minimal fluroscopic exposure. There is also a need for a system and process that allows improved accuracy in performing the wedge resecfion and in placing pins or staples.

SUMMARY

The present invention is applicable not only for knee repair, reconstruction or replacement surgery, but also repair, reconstruction or replacement surgery in connection with any other joint of the body as wellas any other surgical or other operation where it is useful to track position and orientation of body parts, non-body components and/or virtual references such as rotational axes, and to display and output data regarding positioning and orientation of them relative to each other for use in navigation and performance of the operation.

Systems and processes according to one embodiment of the present invention use position and/or orientation tracking sensors such as infrared sensors acting stereoscopically or otherwise to track positions of body parts, surgery-related items such as implements, instrumentation, trial prosthetics, prosthetic components, and virtual constructs or references such as rotational axes which have been calculated and stored based on designation of bone landmarks. Processing capability such as any desired form of computer functionality, whether standalone, networked, or otherwise, takes into account the position and orientation information as to various items in the position sensing field (which may correspond generally or specifically to all or portions or more than all of the surgical field) based on sensed position and orientation of their associated fiducials or based on stored position and/or orientation information. The processing functionality correlates this position and orientation information for each object with stored information regarding the items, such as a computerized fluoroscopic imaged file of a femur or tibia, a wire frame data file for rendering a representation of an instrumentation component, trial prosthesis or actual prosthesis, or a computer generated file relating to a rotational axis or other virtual construct or reference. The processing functionality then displays position and orientation of these objects on a screen or monitor, or otherwise. Thus, systems and processes according to one embodiment of the invention can display and otherwise output useful data relating to predicted or actual position and orientation of body parts, surgically related items, implants, and virtual constructs for use in navigation, assessment, and otherwise performing surgery or other operations.

As one example, images such as fluoroscopy images showing internal aspects of the femur and tibia can be displayed on the monitor in combination with actual or predicted shape, position and orientation of surgical implements, instrumentation components, trial implants, actual prosthetic components, and rotational axes in order to allow the surgeon to properly position and assess performance of various aspects of the tibia being repaired, reconstructed or replaced. The surgeon may navigate tools,

instrumentation, trial prostheses, actual prostheses and other items relative to the tibia in order to perform HTO's more accurately, efficiently, and with better alignment and stability.

Systems and processes according to the present invention can also use the position tracking information and, if desired, data relating to shape and configuration of surgical related items and virtual constructs or references in order to produce numerical data which may be used with or without graphic imaging to perform tasks such as assessing performance of trial prosthetics statically and throughout a range of motion, appropriately modifying tissue such as ligaments to improve such performance and similarly assessing performance of actual prosthetic components which have been placed in the patient for alignment and stability. Systems and processes according to the present invention can also generate data based on position tracking and, if desired, other information to provide cues on screen, aurally or as otherwise desired to assist in the surgery such as suggesting certain bone modification steps based on performance of components as sensed by systems and processes according to the present invention.

According to a preferred embodiment of systems and processes according to the present invention, at least the following steps are involved:

1. Obtain appropriate images such as fluoroscopy images of appropriate body parts such as femur and tibia, the imager being tracked in position via an associated fiducial whose position and orientation is tracked by position/orientation sensors such as stereoscopic infrared (active or passive) sensors according to the present invention.

2. Register tools, instrumentation and other items to be used in surgery, each of which corresponds to a fiducial whose position and orientation can be tracked by the position/orientation sensors.

3. Locating and registering body structure such as designating points on the femur and tibia using a probe associated with a fiducial in order to provide the processing functionality information relating to the body part such as rotational axes.

4. Navigating and positioning instrumentation such as cutting instrumentation in order to modify bone, at least partially using images generated by the processing functionality corresponding to what is being tracked and/or has been tracked, and/or is predicted by the system, and thereby resecting bone effectively, efficiently and accurately.

5. Navigating and positioning items such as pivot pins and, if desired, at the appropriate time discontinuing tracking the position and orientation of the items using the fiducial that is attached to the item and starting to track that position and orientation using the body part fiducial on which the item is installed.

6. Assessing alignment and stability of pivot pins and joint, both statically and dynamically as desired, using images of the body parts in combination with images of the pivot pins or trial components while conducting appropriate rotation, anterior-posterior drawer and flexion/extension tests and automatically storing and calculating results to present data or information which allows the surgeon to assess alignment and stability.

7. Adjusting pivot pins if necessary and adjusting trial components as desired for acceptable alignment and stability.

8. Fixing cutting jigs to the body part at the desired angle as calculated by the system.

9. Assessing alignment and stability of the wedge resection and joint by use of some or all tests mentioned above and/or other tests as desired, adjusting if desired, and otherwise verifying acceptable alignment, stability and performance of the wedge resection, both statically and dynamically.

This process, or processes including it or some of it may be used in any total or partial joint repair, reconstruction or replacement, including knees, hips, shoulders, elbows, ankles and any other desired joint in the body.

Systems and processes according to the present invention represent significant improvement over other previous systems and processes. For instance, systems which use CT and MRI data generally require the

placement of reference frames pre-operatively which can lead to infection at the pin site. The resulting 3D images must then be registered, or calibrated, to the patient anatomy intraoperatively. Current registration methods are less accurate than the fluoroscopic system. These imaging modalities are also more expensive. Some "imageless" systems, or non-imaging systems, require digitizing a large number of points to define the complex anatomical geometries of the knee at each desired site. This can be very time intensive resulting in longer operating room time. Other imageless systems determine the mechanical axis of the knee by performing an intraoperative kinematic motion to determine the center of rotation at the hip, knee, and ankle. This requires placement of reference frames at the iliac crest ofthe pelvis and in or on the ankle. This calculation is also time consuming at the system must find multiple points in different planes in order to find the center of rotation. This is also problematic in patients with pathologic conditions. Ligaments and soft tissues in the arthritic patient are not normal and thus will give a center of rotation that is not desirable for normal knees.

Robotic systems require expensive CT or MRI scans and also require pre-operative placement of tibial markers, usually the day before surgery, or pre-operative construction of tibia surface models. These systems are also much slower, almost doubling operating room time and expense.

None of these systems can effectively track pivot pins during a range of motion and calculate the relative angle of the wedge resection, among other things. Also, none of them currently make suggestions on the appropriate angle or surgical techniques for wedge resection based on reference axes and correction algorithms. Additionally, none of these systems currently track the patella.

An object of certain aspects of the present invention is to use computer processing functionality in combination with imaging and position and/or orientation tracking sensors to present to the surgeon during surgical operations visual and data information useful to navigate, track and/or position implements, instrumentation, and other items and virtual constructs relative to

the human body in order to improve performance of a repaired, replaced or reconstructed bone.

Another object of certain aspects of the present invention is to use computer processing functionality in combination with imaging and position and/or orientation tracking sensors to present to the surgeon during surgical operations visual and data information useful to assess performance of a tibia and certain items positioned therein, for stability, alignment and other factors, and to instrumentation and resection in order to improve such performance of a repaired, reconstructed or replaced bone

Another object of certain aspects of the present invention is to use computer processing functionality in combination with imaging and position and/or orientation tracking sensors to present to the surgeon during surgical operations visual and data information useful to show any or all predicted position and movement of instrumentation and other items and virtual constructs relative to the human body in order to select appropriate angles, resect bone accurately, effectively and efficiently, and thereby improve performance of a repaired, replaced or reconstructed bone.

Other objects, features and advantages of the present invention are apparent with respect to the remainder of this document.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic view of a particular embodiment of systems and processes according to the present invention.

Fig. 2 is a view of a knee prepared for surgery to which fiducials according to one embodiment of the present invention have been attached.

Fig. 3 is a view of a portion of a leg prepared for surgery according to the present invention with a C-arm for obtaining fluoroscopic images associated with a fiducial according to one embodiment of the present invention.

Fig. 4 is a fluoroscopic image of free space rendered on a monitor according to one embodiment of the present invention.

Fig. 5 is a fluoroscopic image of femoral head obtained and rendered according one embodiment of the present invention.

Fig. 6 is a fluoroscopic image of a knee obtained and rendered according to one embodiment of the present invention.

Fig. 7 is a fluoroscopic image of a tibia distal end obtained and rendered according to one embodiment of the present invention.

Fig. 8 is a fluoroscopic image of a lateral view of a knee obtained and rendered according to one embodiment of the present invention.

Fig. 9 is a fluoroscopic image of a lateral view of a knee obtained and rendered according to one embodiment of the present invention.

Fig. 10 is a fluoroscopic image of a lateral view of a tibia distal end obtained and rendered according to one embodiment of the present invention.

Fig. 11 shows a probe according to one embodiment of the present invention being used to register a surgically related component for tracking according to one embodiment of the present invention.

Fig. 12 shows a probe according to one embodiment of the present invention being used to designate landmarks on bone structure for tracking according one embodiment of the present invention.

Fig. 13 is a screen face produced according to one embodiment of the present invention during designation of landmarks to determine a femoral mechanical axis.

Fig. 14 is a screen face produced according to one embodiment of the present invention during designation of landmarks to determine an epicondylar axis.

Fig. 15 is a screen face produced according to one embodiment of the present invention during designation of landmarks to determine an anterior-posterior axis.

Fig. 16 is a screen face according to one embodiment of the present invention showing mechanical and other axes which have been established according to one embodiment of the present invention.

Fig. 17 is another screen face according to one embodiment of the present invention showing mechanical and other axes which have been established according to one embodiment of the present invention.

Fig. 18 shows a pivot pin according to one embodiment of the present invention being placed in the tibia.

Fig. 19 shows tibial cutting jigs according to one embodiment of the present invention.

Fig. 20 shows proximal and distal cutting jigs according to one embodiment of the present invention being placed on the tibia around the pivot pin.

Fig. 21 is a screen face produced according to one embodiment of the present invention which assists in navigation and/or placement of a distal cutting jig.

Fig. 22 shows a tibia that has been stapled after a closed wedge resection.

DETAILED DESCRIPTION

Systems and processes according to a preferred embodiment of the present invention use computer capacity, including standalone and/or networked, to store data regarding spatial aspects of surgically related items and virtual constructs or references including body parts, implements, instrumentation, trial components, prosthetic components and rotational axes of body parts. Any or all of these may be physically or virtually connected to or incorporate any desired form of mark, structure, component, or other fiducial or reference device or technique which allows position and/or orientation of the item to which it is attached to be sensed and tracked, preferably in three dimensions of translation and three degrees of rotation as well as in time if desired. In a preferred embodiment, orientation of the elements on a particular fiducial varies from one fiducial to the next so that sensors according to the present invention may distinguish between various components to which the fiducials are attached in order to correlate for display and other purposes data files or images of the components. In a referred embodiment, "fidicuals" are reference frames each containing at least three, preferably four, sometimes more, reflective elements such as spheres reflective of lightwave or infrared energy, or active elements such as LED's. In a preferred embodiment of the present invention, some fiducials use

reflective elements and some use active elements, both of which may be tracked by preferably two, sometimes more infrared sensors whose output may be processed in concert to geometrically calculate position and orientation of the item to which the fiducial is attached.

Position/orientation tracking sensors and fiducials need not be confined to the infrared spectrum. Any electromagnetic, electrostatic, light, sound, radiofrequency or other desired technique may be used. Alternatively, each item such as a surgical implement, instrumentation component, trial component, implant component or other device may contain its own "active" fiducial such as a microchip with appropriate field sensing or position/orientation sensing functionality and communications link such as spread spectrum RF link, in order to report position and orientation of the item. Such active fiducials, or hybrid active/passive fiducials such as transponders can be implanted in the body parts or in any of the surgically related devices mentioned above, or conveniently located at their surface or otherwise as desired. Fiducials may also take the form of conventional structures such as a screw driven into a bone, or any other three dimensional item attached to another item, position and orientation of such three dimensional item able to be tracked in order to track position and orientation of body parts and surgically related items. Hybrid fiducials may be partly passive, partly active such as inductive components or transponders which respond with a certain signal or data set when queried by sensors according to the present invention.

Systems and processes according to a preferred embodiment of the present invention employ a computer to calculate and store reference axes of body components such as in a HTO for example, the mechanical axis of the femur and tibia. From these axes such systems track the position of the instrumentation and osteotomy guides so that bone resections will locate the implant position optimally, usually aligned with the mechanical axis. Furthermore, during trial reduction of the knee, the systems provide feedback on the balancing of the ligaments in a range of motion and under varus/valgus, anterior/posterior and rotary stresses and can suggest or at least provide more accurate information than in the past about which

ligaments the surgeon should release in order to obtain correct balancing, alignment and stability. Systems and processes according to the present invention can also suggest modifications to implant size, positioning, and other techniques to achieve optimal kinematics. Systems and processes according to the present invention can also include databases of information regarding tasks such as ligament balancing, in order to provide suggestions to the surgeon based on performance of test results as automatically calculated by such systems and processes.

FIG. 1 is a schematic view showing one embodiment of a system according to the present invention and one version of a setting according to the present invention in which surgery on a knee, in this case a High Tibial Osteotomy, may be performed. Systems and processes according to the present invention can track various body parts such as tibia 10 and femur 12 to which fiducials of the sort described above or any other sort may be implanted, attached, or otherwise associated physically, virtually, or otherwise. In the embodiment shown in FIG. 1, fiducials 14 are structural frames some of which contain reflective elements, some of which contain LED active elements, some of which can contain both, for tracking using stereoscopic infrared sensors suitable, at least operating in concert, for sensing, storing, processing and/or outputting data relating to ("tracking") position and orientation of fiducials 14 and thus components such as 10 and 12 to which they are attached or otherwise associated. Position sensor 16, as mentioned above, may be any sort of sensor functionality for sensing position and orientation of fiducials 14 and therefore items with which they are associated, according to whatever desired electrical, magnetic, electromagnetic, sound, physical, radio frequency, or other active or passive technique. In the preferred embodiment, position sensor 16 is a pair of infrared sensors disposed on the order of a meter, sometimes more, sometimes less, apart and whose output can be processed in concert to provide position and orientation information regarding fiducials 14.

In the embodiment shown in FIG. 1, computing functionality 18 can include processing functionality, memory functionality, input/output

functionality whether on a standalone or distributed basis, via any desired standard, architecture, interface and/or network topology. In this embodiment, computing functionality 18 is connected to a monitor on which graphics and data may be presented to the surgeon during surgery. The screen preferably has a tactile interface so that the surgeon may point and click on screen for tactile screen input in addition to or instead of, if desired, keyboard and mouse conventional interfaces. Additionally, a foot pedal 20 or other convenient interface may be coupled to functionality 18 as can any other wireless or wireline interface to allow the surgeon, nurse or other desired user to control or direct functionality 18 in order to, among other things, capture position/orientation information when certain components are oriented or aligned properly. Items 22 such as trial components, instrumentation components may be tracked in position and orientation relative to body parts 10 and 12 using fiducials 14.

Computing functionality 18 can process, store and output on monitor 24 and otherwise various forms of data which correspond in whole or part to body parts 10 and 12 and other components for item 22. For example, in the embodiment shown in FIG. 1, body parts 10 and 12 are shown in cross-section or at least various internal aspects of them such as bone canals and surface structure are shown using fluoroscopic images. These images are obtained using a C-arm attached to a fiducial 14. The body parts, for example, tibia 10 and femur 12, also have fiducials attached. When the fluoroscopy images are obtained using the C-arm with fiducial 14, a position/orientation sensor 16 "sees" and tracks the position of the fluoroscopy head as well as the positions and orientations of the tibia 10 and femur 12. The computer stores the fluoroscopic images with this position/orientation information, thus correlating position and orientation of the fuoroscopic image relative to the relevant body part or parts. Thus, when the tibia 10 and corresponding fiducial 14 move, the computer automatically and correspondingly senses the new position of tibia 10 in space and can correspondingly move implements, instruments, references, trials and/or implants on the monitor 24 relative to the image of tibia 10. Similarly, the

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image of the body part can be moved, both the body part and such items may be moved, or the on screen image otherwise presented to suit the preferences of the surgeon or others and carry out the imaging that is desired. Similarly, when an item 22 such as a pivot pin that is being tracked moves, its image moves on monitor 24 so that the monitor shows the item 22 in proper position and orientation on monitor 24 relative to the femur 12. The pin 22 can thus appear on the monitor 24 in proper or improper alignment with respect to the mechanical axis and other features of the femur 12, as if the surgeon were able to see into the body in order to navigate and position the pin 22 properly.

The computer functionality 18 can also store data relating to configuration, size and other properties of items 22 such as implements, instrumentation, trial components, implant components and other items used in surgery. When those are introduced into the field of position/orientation sensor 16, computer functionality 18 can generate and display overlain or in combination with the fluoroscopic images of the body parts 10 and 12, computer generated images of implements, instrumentation components, trial components, implant components and other items 22 for navigation, positioning, assessment and other uses.

Additionally, computer functionality 18 can track any point in the position/orientation sensor 16 field such as by using a designator or a probe 26. The probe also can contain or be attached to a fiducial 14. The surgeon, nurse, or other user touches the tip of probe 26 to a point such as a landmark on bone structure and actuates the foot pedal 20 or otherwise instructs the computer 18 to note the landmark position. The position/orientation sensor 16 "sees" the position and orientation of fiducial 14 "knows" where the tip of probe 26 is relative to that fiducial 14 and thus calculates and stores, and can display on monitor 24 whenever desired and in whatever form or fashion or color, the point or other position designated by probe 26 when the foot pedal 20 is hit or other command is given. Thus, probe 26 can be used to designate landmarks on bone structure in order to allow the computer 18 to store and track, relative to movement of the bone fiducial 14, virtual or logical information such as mechanical axis 28, medial laterial axis 30 and

anterior/posterior axis 32 of femur 12, tibia 10 and other body parts in addition to any other virtual or actual construct or reference.

Systems and processes according to an embodiment of the present invention such as the subject of Figs. 2-22, can use the so-called FluoroNAV system and software provided by Medtronic Sofamor Danek Technologies. Such systems or aspects of them are disclosed in USPNs 5,383,454; 5,871,445; 6,146,390; 6,165,81; 6,235,038 and 6,236,875, and related (under 35 U.S.C. Section 119 and/or 120) patents, which are all incorporated herein by this reference. Any other desired systems can be used as mentioned above for imaging, storage of data, tracking of body parts and items and for other purposes.

The FluoroNav system requires the use of reference frame type fiducials 14 which have four and in some cases five elements tracked by infrared sensors for position/orientation of the fiducials and thus of the body part, implement, instrumentation, trial component, implant component, or other device or structure being tracked. Such systems also use at least one probe 26 which the surgeon can use to select, designate, register, or otherwise make known to the system a point or points on the anatomy or other locations by placing the probe as appropriate and signaling or commanding the computer to note the location of, for instance, the tip of the probe. The FluoroNav system also tracks position and orientation of a Carm used to obtain fluoroscopic images of body parts to which fiducials have been attached for capturing and storage of fluoroscopic images keyed to position/orientation information as tracked by the sensors 16. Thus, the monitor 24 can render fluoroscopic images of bones in combination with computer generated images of virtual constructs and references together with implements, instrumentation components, trial components, implant components and other items used in connection with surgery for navigation, resection of bone, assessment and other purposes.

FIGS. 2-22 are various views associated with High Tibial Osteotomy surgery processes according to one particular embodiment and version of the present invention being carried out with the FluoroNav system referred to

above. FIG. 2 shows a human knee in the surgical field, as well as the corresponding femur and tibia, to which fiducials 14 have been rigidly attached in accordance with this embodiment of the invention. Attachment of fiducials 14 preferably is accomplished using structure that withstands vibration of surgical saws and other phenomenon which occur during surgery without allowing any substantial movement of fiducial 14 relative to body part being tracked by the system.

FIG. 3 shows fluoroscopy images being obtained of the body parts with fiducials 14 attached. The fiducial 14 on the fluoroscopy head in this embodiment is a cylindrically shaped cage which contains LEDs or "active" emitters for tracking by the sensors 16. Fiducials 14 attached to tibia 10 and femur 12 can also be seen. The fiducial 14 attached to the femur 12 uses LEDs instead of reflective spheres and is thus active, fed power by the wire seen extending into the bottom of the image.

FIGS. 4-10 are fluoroscopic images shown on monitor 24 obtained with position and/or orientation information received by, noted and stored within computer 18. FIG. 4 is an open field with no body part image, but which shows the optical indicia which may be used to normalize the image obtained using a spherical fluoroscopy wave front with the substantially flat surface of the monitor 24. FIG. 5 shows an image of the femur 12 head. This image is taken in order to allow the surgeon to designate the center of rotation of the femoral head for purposes of establishing the mechanical axis and other relevant constructs relating to of the femur according to which the wedge of bone will ultimately be resected. Such center of rotation can be established by articulating the femur within the acetabulum or a prosthesis to capture a number of samples of position and orientation information and thus in turn to allow the computer to calculate the average center of rotation. The center of rotation can be established by using the probe and designating a number of points on the femoral head and thus allowing the computer to calculate the geometrical center or a center which corresponds to the geometry of points collected. Additionally, graphical representations such as controllably sized circles displayed on the monitor can be fitted by the surgeon to the shape of

the femoral head on planar images using tactile input on screen to designate the centers according to that graphic, such as are represented by the computer as intersection of axes of the circles. Other techniques for determining, calculating or establishing points or constructs in space, whether or not corresponding to bone structure, can be used in accordance with the present invention.

FIG. 5 shows a fluoroscopic image of the femoral head while FIG. 6 shows an anterior/posterior view of the knee which can be used to designate landmarks and establish axes or constructs such as the mechanical axis or other rotational axes. FIG. 7 shows the distal end of the tibia and FIG. 8 shows a lateral view of the knee. FIG. 9 shows another lateral view of the knee while FIG. 10 shows a lateral view of the distal end of the tibia.

Registration of Surgically Related Items

FIGS. 11 shows designation or registration of items 22 which will be used in surgery. Registration simply means, however it is accomplished, ensuring that the computer knows which body part, item or construct corresponds to which fiducial or fiducials, and how the position and orientation of the body part, item or construct is related to the position and orientation of its corresponding fiducial or a fiducial attached to an impactor or other other component which is in turn attached to an item. Such registration or designation can be done before or after registering bone or body parts as discussed with respect to FIGS. 4 – 10. FIG. 11 shows a technician designating with probe 26 an item 22 such as an instrument component to which fiducial 14 is attached. The sensor 16 "sees" the position and orientation of the fiducial 14 attached to the item 22 and also the position and orientation of the fiducial 14 attached to the probe 26 whose tip is touching a landmark on the item 22. The technician designates onscreen or otherwise the identification of the item 22 and then activates the foot pedal or otherwise instructs the computer to correlate the data corresponding to such identification, such as data needed to represent a particular cutting jig, with the particularly shaped fiducial 14 attached to the cutting jig. The computer has then stored identification, position and orientation information relating to

the fiducial for item 22 correlated with the data such as configuration and shape data for the item 22 so that upon registration, when sensor 16 tracks the item 22 fiducial 14 in the infrared field, monitor 24 can show the item 22 moving and turning, and properly positioned and oriented relative to the body part which is also being tracked.

Registration of Anatomy and Constructs

Similarly, the mechanical axis and other axes or constructs of body parts 10 and 12 can also be "registered" for tracking by the system. Again, the system has employed a fluoroscope to obtain images of the femoral head, knee and ankle of the sort shown in FIGS. 4-10. The system correlates such images with the position and orientation of the C-arm and the patient anatomy in real time as discussed above with the use of fiducials 14 placed on the body parts before image acquisition and which remain in position during the surgical procedure. Using these images and/or the probe, the surgeon can select and register in the computer 18 the center of the femoral head and ankle in orthogonal views, usually anterior/posterior and lateral, on a touch screen. The surgeon uses the probe to select any desired anatomical landmarks or references at the operative site of the knee or on the skin or surgical draping over the skin, as on the ankle. These points are registered in three dimensional space by the system and are tracked relative to the fiducials on the patient anatomy which are preferably placed intraoperatively. FIG. 12 shows the surgeon using probe 26 to designate or register landmarks on the condylar portion of femur 12 using probe 26 in order to feed to the computer 18 the position of one point needed to determine, store, and display the epicondylar axis. (See FIG. 14 which shows the epicondylar axis and the anterior-posterior plane and for lateral plane.) Although registering points using actual bone structure such as in FIG. 12 is one preferred way to establish the axis, a cloud of points approach by which the probe 26 is used to designate multiple points on the surface of the bone structure can be employed, as can moving the body part and tracking movement to establish a center of rotation as discussed above. Once the center of rotation for the femoral head and the condylar component have been registered, the

computer is able to calculate, store, and render, and otherwise use data for, the mechanical axis of the femur 12.

FIG. 13 shows the onscreen images being obtained when the surgeon registers certain points on the bone surface using the probe 26 in order to establish the femoral mechanical axis. The tibial mechanical axis is then established by designating points to determine the centers of the proximal and distal ends of the tibia so that the mechanical axis can be calculated, stored, and subsequently used by the computer 18. FIG. 14 shows designated points for determining the epicondylar axis, both in the anterior/posterior and lateral planes while FIG. 15 shows such determination of the anterior-posterior axis as rendered onscreen. The posterior condylar axis is also determined by designating points or as otherwise desired, as rendered on the computer generated geometric images overlain or displayed in combination with the fluoroscopic images, all of which are keyed to fiducials 14 being tracked by sensors 16.

FIG. 16 is an onscreen image showing the anterior-posterior axis, epicondylar axis and posterior condylar axis from points which have been designated as described above. These constructs are generated by the computer 18 and presented on monitor 24 in combination with the fluoroscopic images of the femur 12, correctly positioned and oriented relative thereto as tracked by the system. In the fluoroscopic/computer generated image combination shown at left bottom of FIG. 16, a "sawbones" knee as shown in certain drawings above which contains radio opaque materials is represented fluoroscopically and tracked using sensor 16 while the computer generates and displays the mechanical axis of the femur 12 which runs generally horizontally. The epicondylar axis runs generally vertically, and the anterior/posterior axis runs generally diagonally. The image at bottom right shows similar information in a lateral view. Here, the anterior-posterior axis runs generally horizontally while the epicondylar axis runs generally diagonally, and the mechanical axis generally vertically.

FIG. 16, as is the case with a number of screen presentations generated and presented by the system of FIGS. 4-22, also shows at center a

list of landmarks to be registered in order to generate relevant axes and constructs useful in navigation, positioning and assessment during surgery. Textural cues may also be presented which suggest to the surgeon next steps in the process of registering landmarks and establishing relevant axes. Such instructions may be generated as the computer 18 tracks, from one step to the next, registration of items 22 and bone locations as well as other measures being taken by the surgeon during the surgical operation.

FIG. 17 shows mechanical, lateral, anterior-posterior axes for the tibia according to points are registered by the surgeon.

Wedge Resection

After the mechanical axis and other rotation axes and constructs relating to the femur and tibia are established, instrumentation can be properly oriented to resect or modify bone in order to properly resect a bone wedge according to the embodiment of the invention shown in FIGS. 4-22. Instrumentation such as, for instance, cutting jigs, to which fiducials 14 are mounted, can be employed. The system can then track instrumentation as the surgeon manipulates it for optimum positioning. In other words, the surgeon can "navigate" the instrumentation for optimum positioning using the system and the monitor. In this manner, instrumentation may be positioned according to the system of this embodiment in order to align the ostetomies to the mechanical and rotational axes or reference axes. The touchscreen 24 can then also display the instrument such as the cutting jig and/or the pivot pin relative to the cutting jig during this process, in order, among other things, properly to resect a wedge of bone. As the cutting jig moves, the varus/valgus, flexion/extension and internal/external rotation of the relative cutting jig position can be calculated and shown with respect to the referenced axes; in the preferred embodiment, this can be done at a rate of six cycles per second or faster. The cutting jig position is then fixed in the computer and physically and the bone wedge resections are made.

Fig. 18 shows the placement of a pivot pin to which a fiducial is attached via a drill sleeve. The system navigates the placement of a pivot pin at a level of 1 cm from the medial cortex of the tibia and 1 cm below the level

of the tibial plateau. The pin is placed perpendicular to the frontal plane and parallel to the sagittal plane. The pivot pin acts as an intersection point for two resection planes of the wedge.

Fig. 19 shows tibial cutting jigs. The system navigates two cutting jigs on an assembly that slides over the pivot pin. The proximal jig is aligned parallel to the tibial plateau and fixed to the tibia, as shown in Fig. 20. The distal jig is then placed radially about the pivot pin.

Fig. 21 also shows other information relevant to the surgeon such as the name of the component being overlain on the tibialimage, suggestions or instructions at the lower left, and angle of the rod in varus/valgus and extension relative to the axes. Any or all of this information can be used to navigate and position the cutting jig relative to the tibia.

Navigation, Placement and Assessment of Angle

Once the distal jig is placed radially about the pivot pin, the jig is adjusted radially to the desired angle calculated by the system based on desired correction algorithms and reference axes. The distal jig is fixed to the tibia and the bone wedge is resected. After removal of the wedge, either the opening is reduced and plated or stapled for a closed wedge procedure, as shown in Fig. 22, or it is braced open with a plate for an open wedge procedure. The open wedge is then grafted to fill the void.

During the wedge resection process, instrument positioning process or at any other desired point in surgical or other operations according to the present invention, the system can transition or segue from tracking a component according to a first fiducial to tracking the component according to a second fiducial. Thus, the pivot pin can be mounted on an drill sleeve to which a fiducial 14 is attached. The pivot pin is installed and positioned using the drill sleeve. The computer 18 "knows" the position and orientation of the pin relative to the fiducial on the drill sleeve (such as by prior registration of the component attached to the drill sleeve) so that it can generate and display the image of the pivot pin on screen 24 ovelaid on the fluoroscopic image of the tibia. At any desired point in time, before, during or after the pivot pin is properly placed in the tibia to align with mechanical axis and according to

proper orientation relative to other axes, the system can beinstructed by foot pedal or otherwise to begin tracking the position of the pivot pin using the fiducial attached to the tibia rather than the one attached to the drill sleeve. According to the preferred embodiment, the sensor 16 "sees" at this point in time both the fiducials on the drill sleeve and the tibia 12 so that it already "knows" the position and orientation of the pivot pin relative to the fiducial on the drill sleeve and is thus able to calculate and store for later use the position and orientation of the pivot pin relative to the tibia 12 fiducial. Once this "handoff" happens, the drill sleeve can be removed and the pivot pin tracked with the tibia fiducial 14 as part of or moving in concert with the tibia 12. Similar handoff procedures may be used in any other instance as desired in accordance with the present invention.

At the end of the case, all alignment information can be saved for the patient file. This is of great assistance to the surgeon due to the fact that the outcome of implant positioning can be seen before any resectioning has been done on the bone. The system is also capable of tracking the patella and resulting placement of cutting guides and the patellar trial position. The system then tracks alignment of the patella with the patellar femoral groove and will give feedback on issues, such as, patellar tilt.

The tracking and image information provided by systems and processes according to the present invention facilitate telemedical techniques, because they provide useful images for distribution to distant geographic locations where expert surgical or medical specialists may collaborate during surgery. Thus, systems and processes according to the present invention can be used in connection with computing functionality 18 which is networked or otherwise in communication with computing functionality in other locations, whether by PSTN, information exchange infrastructures such as packet switched networks including the Internet, or as otherwise desire. Such remote imaging may occur on computers, wireless devices, videoconferencing devices or in any other mode or on any other platform which is now or may in the future be capable of rending images or parts of them produced in accordance with the present invention. Parallel communication links such as

switched or unswitched telephone call connections may also accompany or form part of such telemedical techniques. Distant databases such as online catalogs of implant suppliers or prosthetics buyers or distributors may form part of or be networked with functionality 18 to give the surgeon in real time access to additional options for implants which could be procured and used during the surgical operation.

What is claimed is:

1. A process for performing high tibial osteotomy surgical operations on portions of a knee joint, comprising:

(a) obtaining at least one image of a body part forming a portion of said joint with an imager, wherein the body part and the imager are each attached to a fiducial capable of being tracked by at least one position sensor;

(b) registering a high tibial osteotomy surgical instrument attached to a fiducial capable of being tracked by at least one position sensor;

(c) using a computer which receives signals from the at least one sensor, tracking position and orientation of the surgical instrument relative to the body part;

(d) generating and displaying on a monitor associated with the computer a visual image of the instrument properly positioned and oriented relative to the body part;

(e) navigating the surgical instrument relative to the body part and attaching the surgical instrument to the body part according to the image;

(f) modifying the body part using the surgical instrument attached to the body part; and

(g) assessing performance of the joint using images displayed on said monitor.

2. A process according to claim 1 in which the high tibial ostemtomy surgical instrument is a pivot pin.

3. A process according to claim 1 in which the high tibial osteotomy surgical instrument is a cutting jig.

4. A system for performing high tibial osteotomy surgical operations on portions of a knee joint comprising:

(a) an imager for obtaining an image of at least portions of the knee joint, wherein the imager and at least one bone forming part of the knee joint are each attached to a fiducial capable of being tracked by a position sensor;

(b) at least one position sensor adapted to track position of said fiducials;

(c) a computer adapted to store at least one image of at least portions of the knee joint and to receive information from said at least one sensor in order to track position and orientation of said fiducials and thus the knee joint;

(d) a high tibial osteotomy surgical instrument component adapted to be attached to bone forming part of the knee joint using a tool, said tool attached to a fiducial, whereby the position of the surgical instrument component is capable of being tracked by said sensor and the position and orientation of the surgical instrument component is capable of being tracked by said computer;

(e) a monitor adapted to receive information from the computer in order to display at least one image of the surgical instrument component, positioned and oriented relative to the knee joint for navigation and positioning of the surgical instrument component relative to the knee joint.

5. A system according to claim 4 in which the instrument component is a pivot pin.

6. A system according to claim 4 in which the instrument component is a cutting jig.

7. A system according to claim 4 in which the component corresponds to a femur.

8. A system according to claim 4 in which the component corresponds to a tibia.

9. A system according to claim 4 in which the imager comprises one of a C-arm fluoroscope, a CT scanner, and an MRI machine.

10. A system according to claim 4 in which the fiducials comprise one of active fiducials, passive fiducials and hybrid active/passive fiducials.

11. A system according to claim 4 in which the position sensors comprise one of infrared sensors, electromagnetic sensors, electrostatic sensors, light sensors, sound sensors, and radiofrequency sensors.

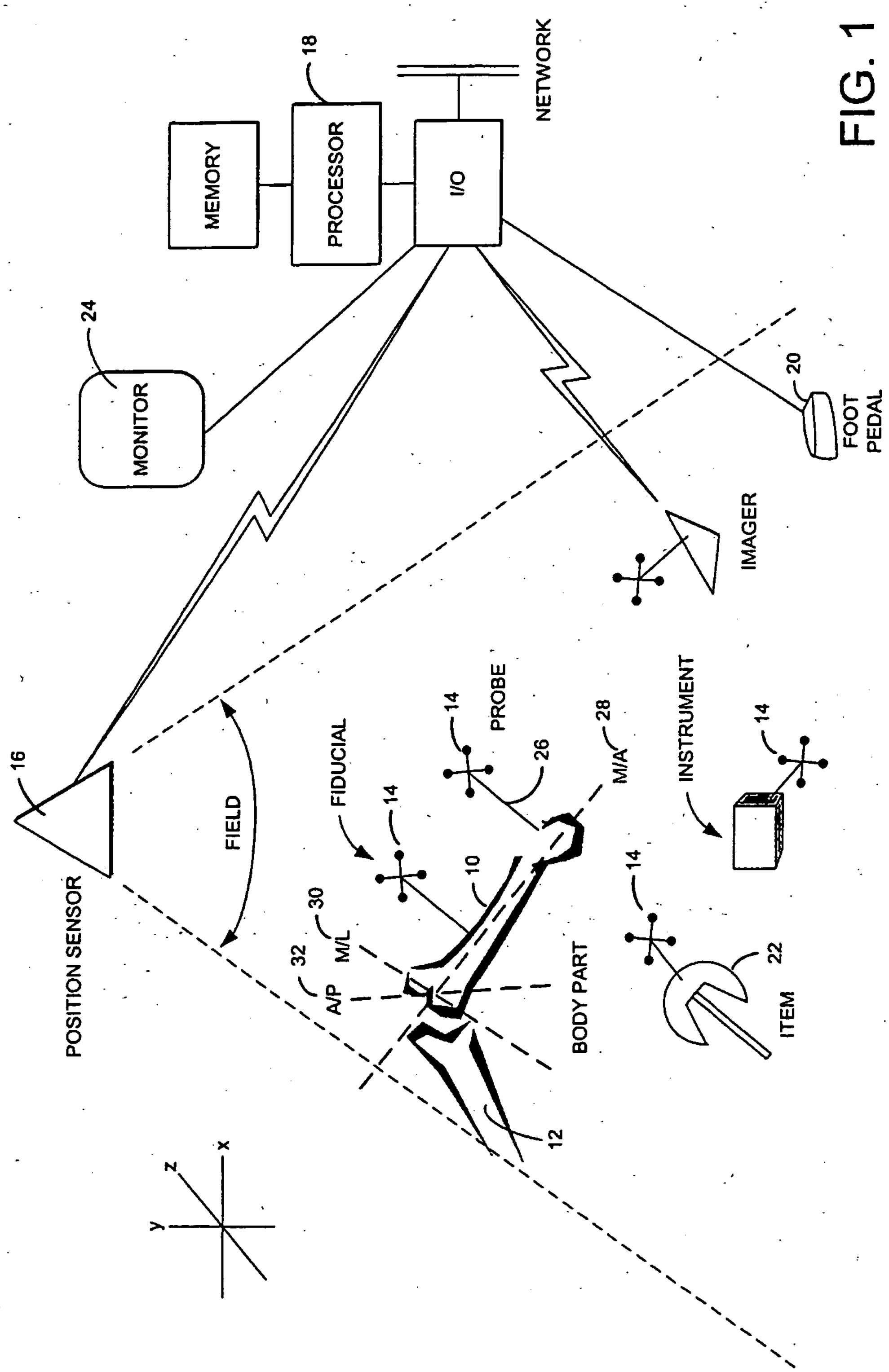
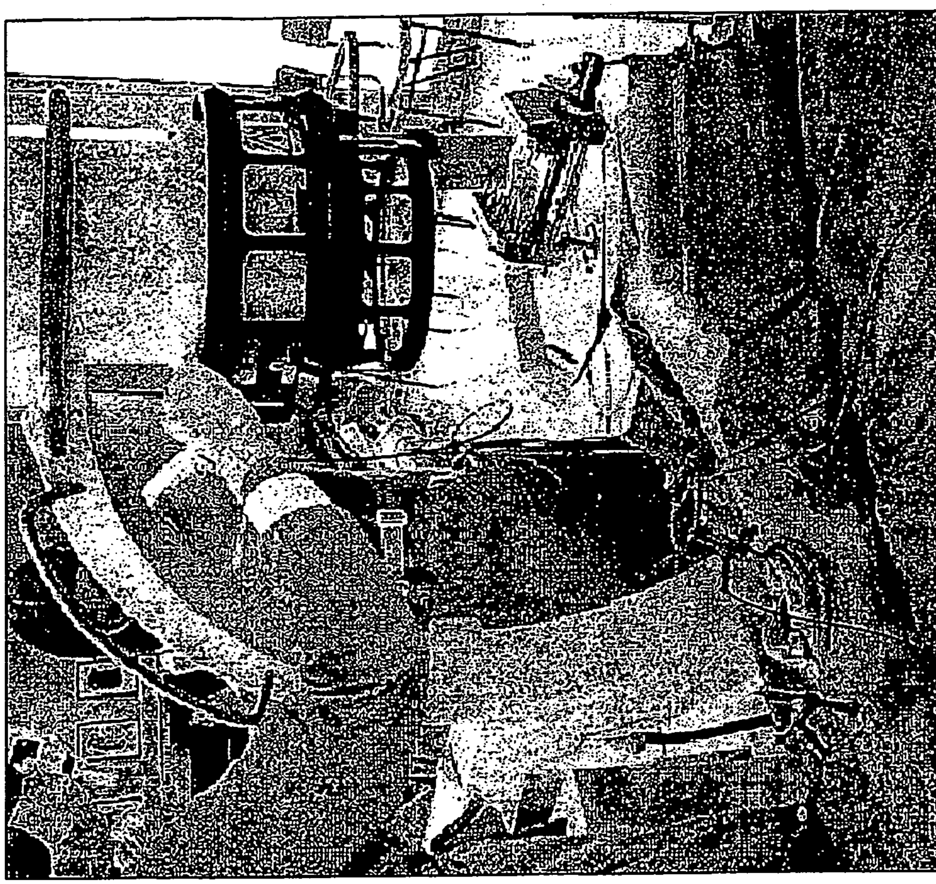

MEMORY
PROCESSOR
18
I/O
NETWORK
24
MONITOR
20
FOOT PEDAL
IMAGER
16
POSITION SENSOR
FIELD
FIDUCIAL
14
PROBE
26
28
M/A
INSTRUMENT
10
30
M/L
32
A/P
BODY PART
22
ITEM
12
x
y
z

FIG. 1

Fig. 2



14

Fig. 3

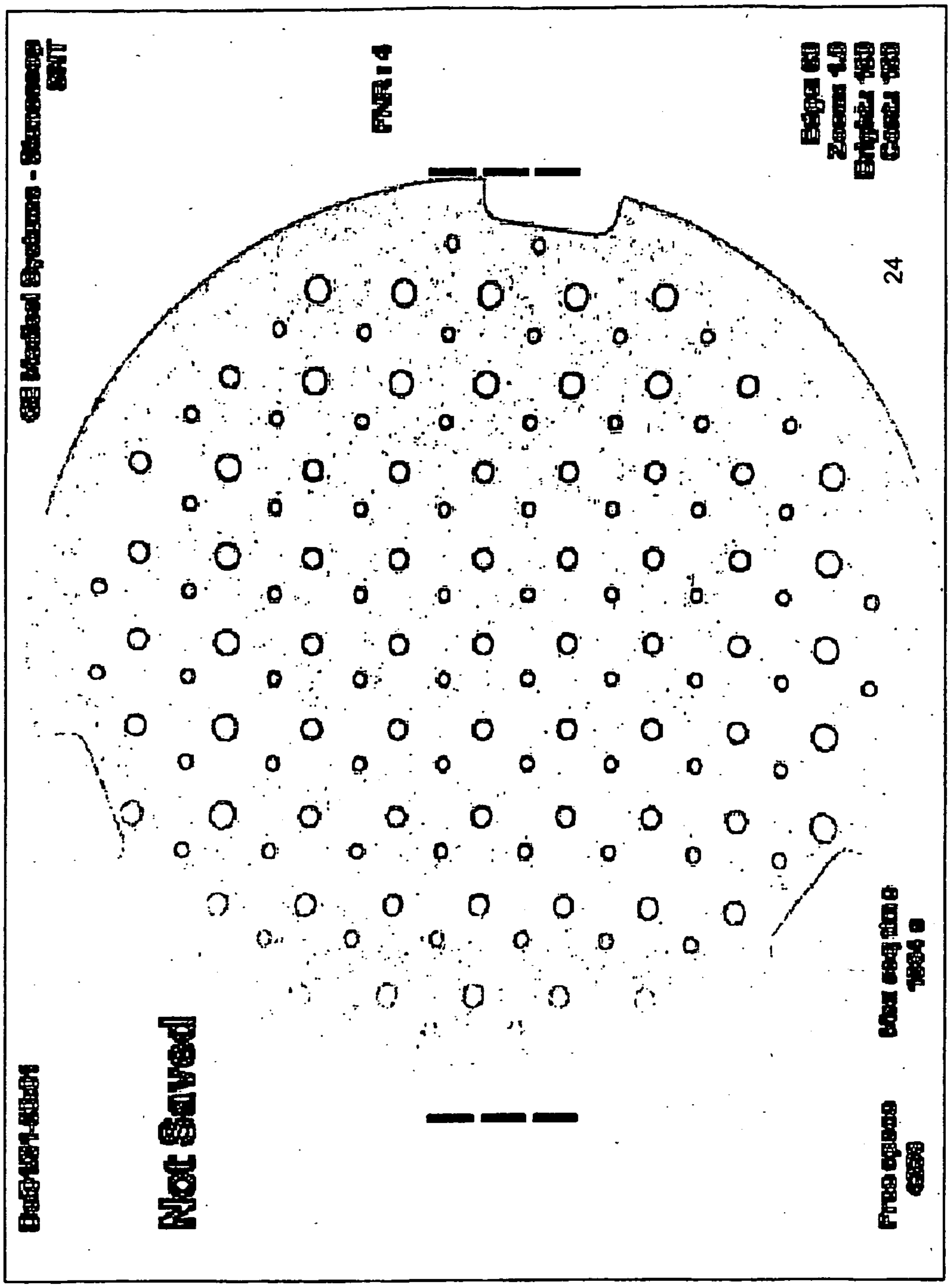


Fig. 4

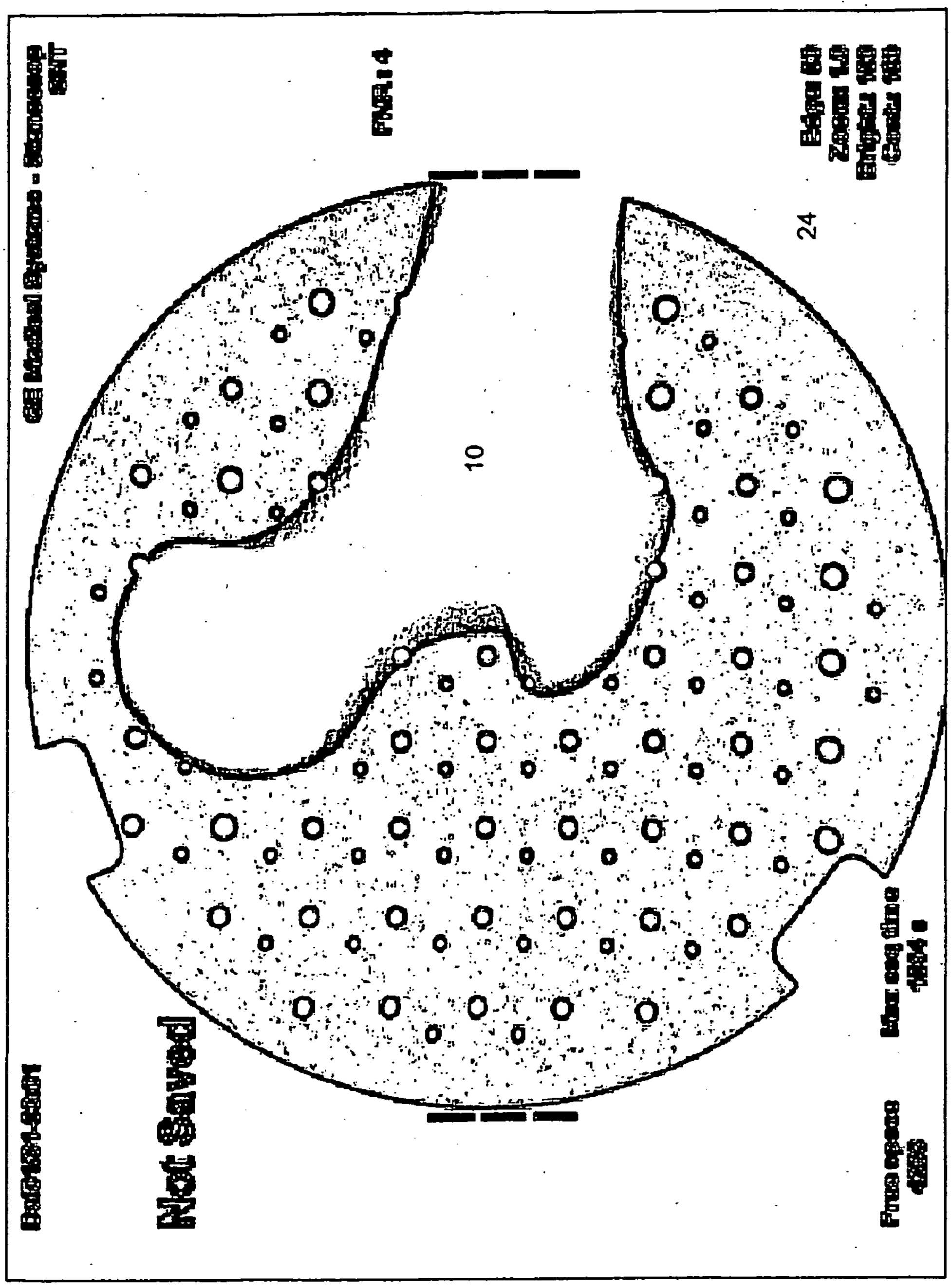


Fig. 5

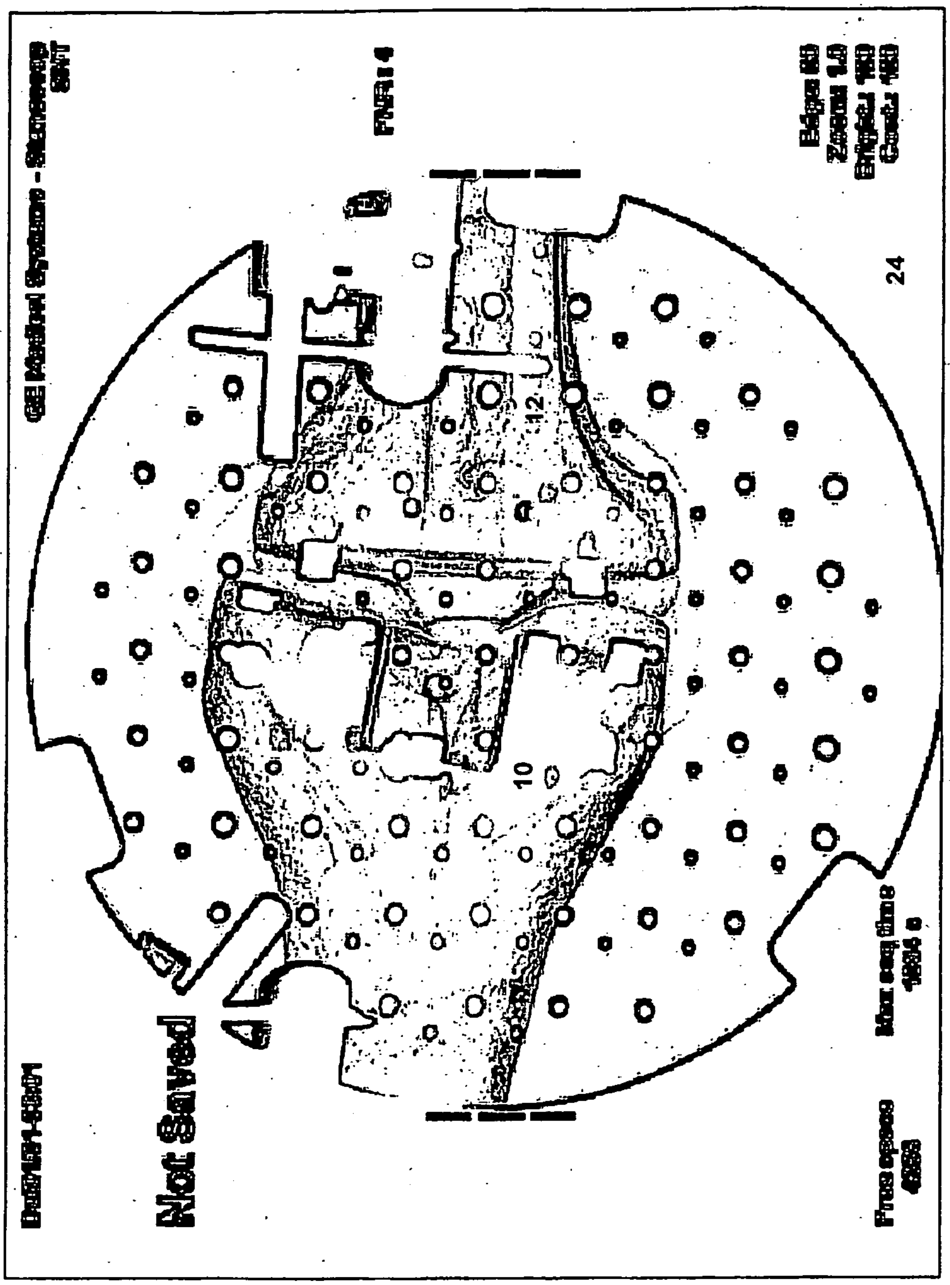


Fig. 6

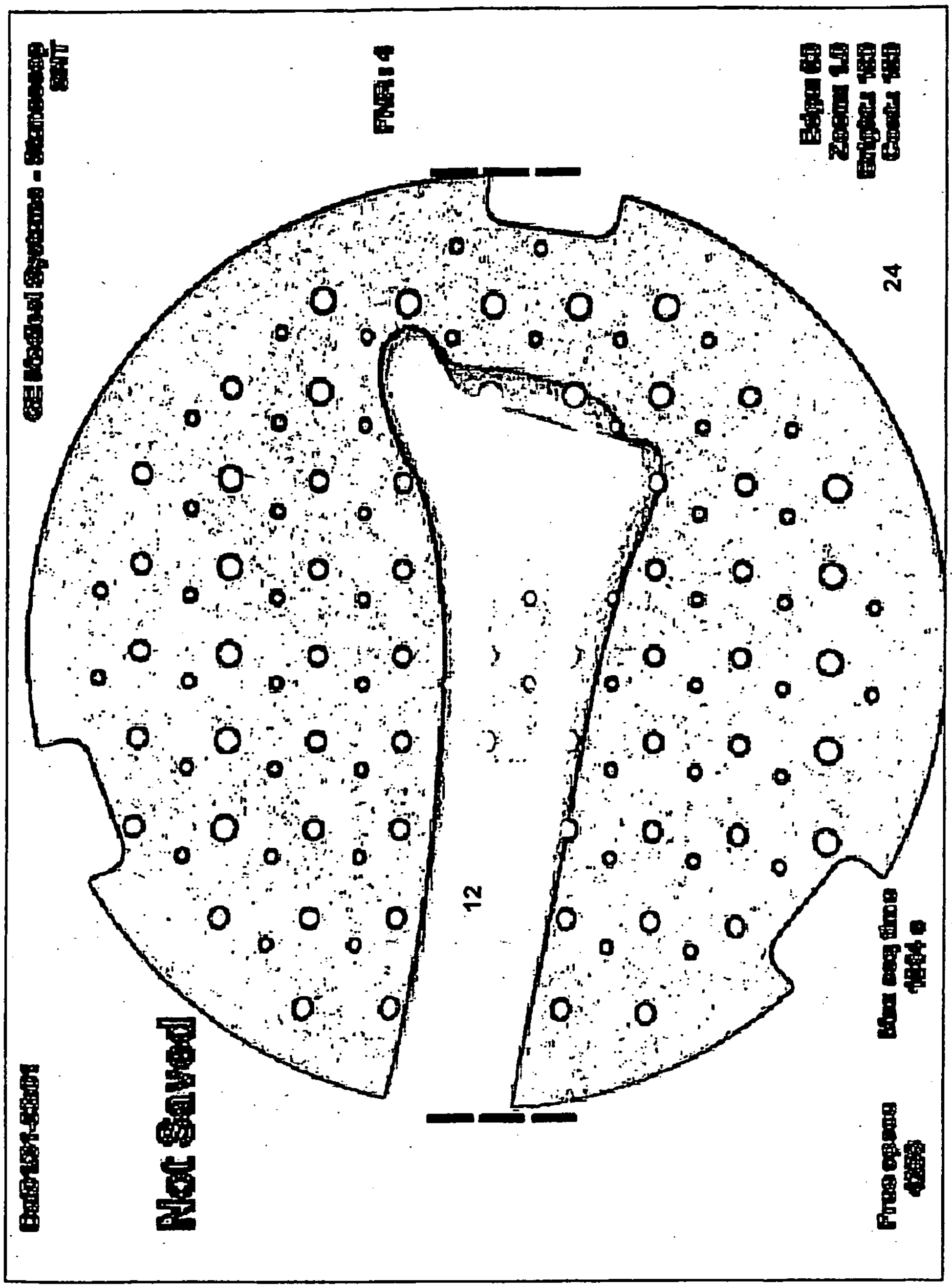


Fig. 7

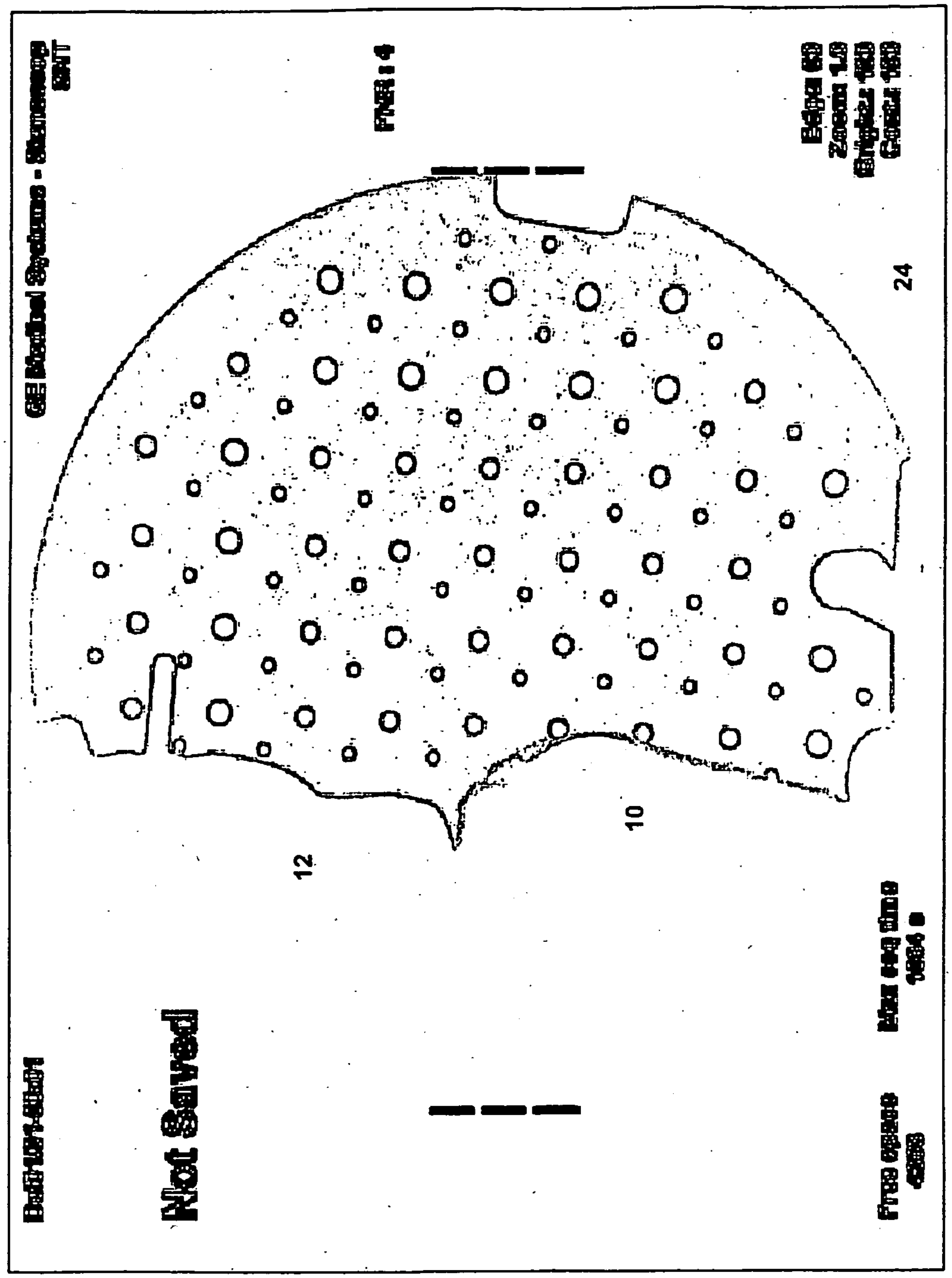


Fig. 8

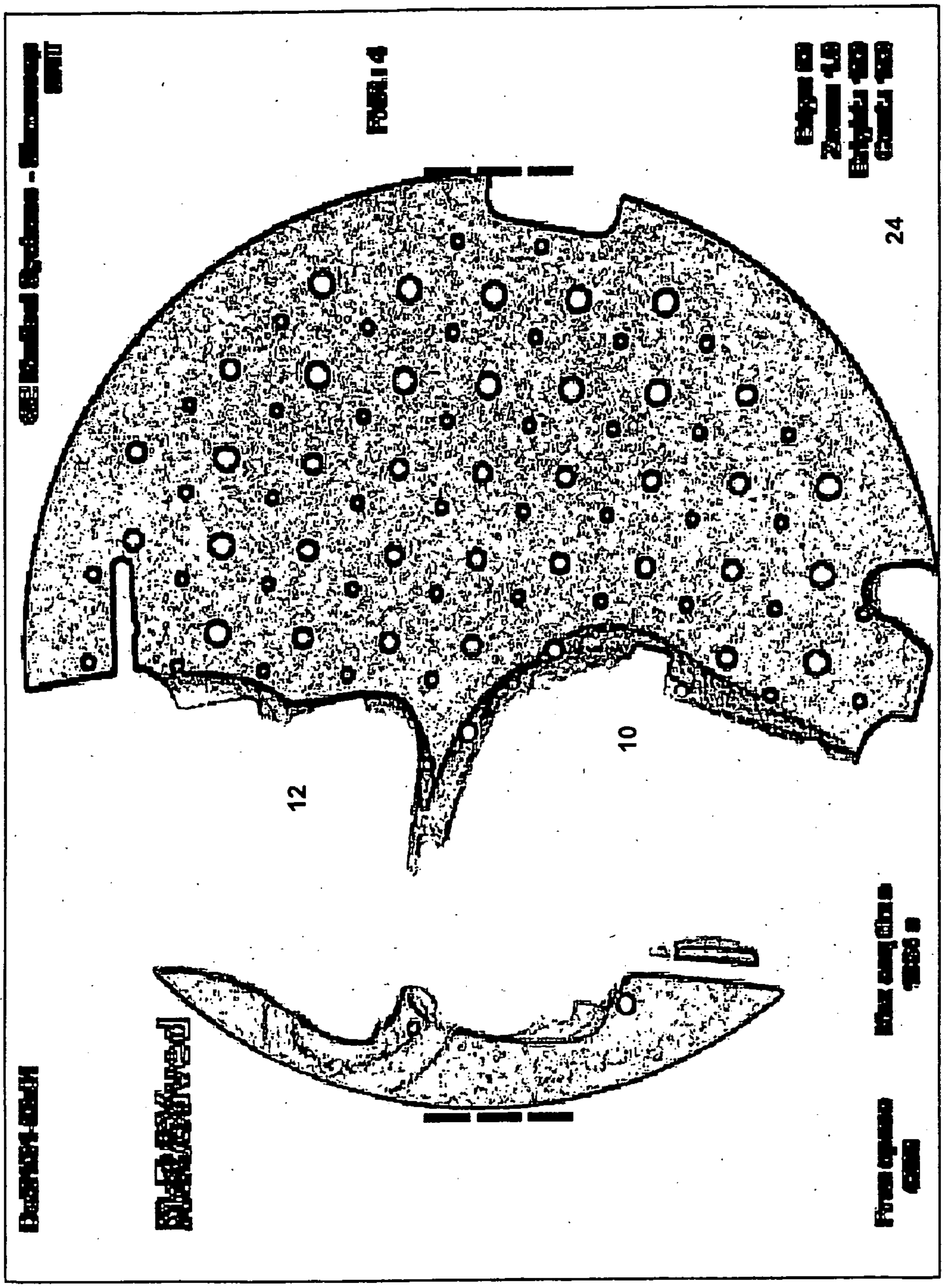


Fig. 9

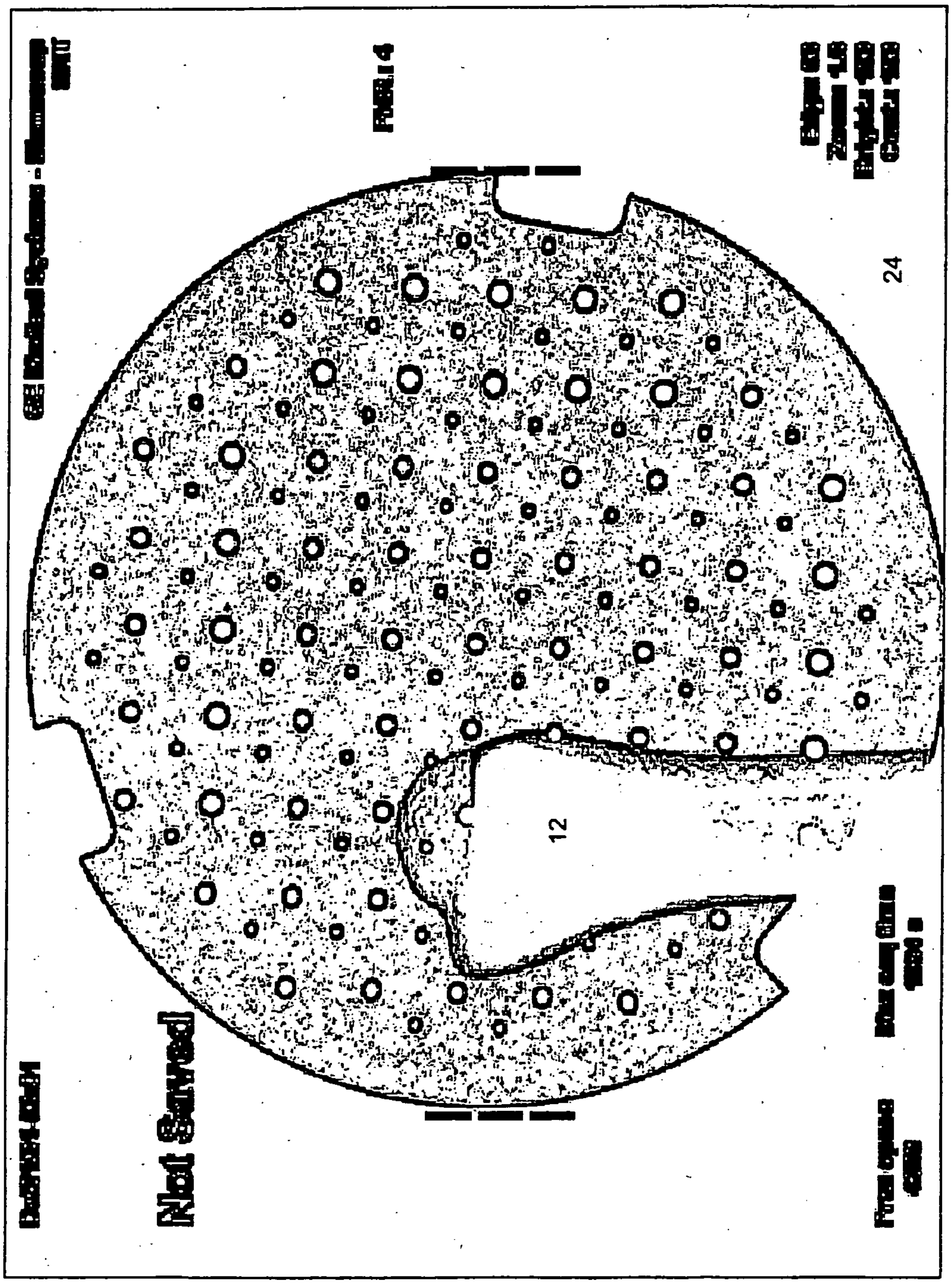


Fig. 10

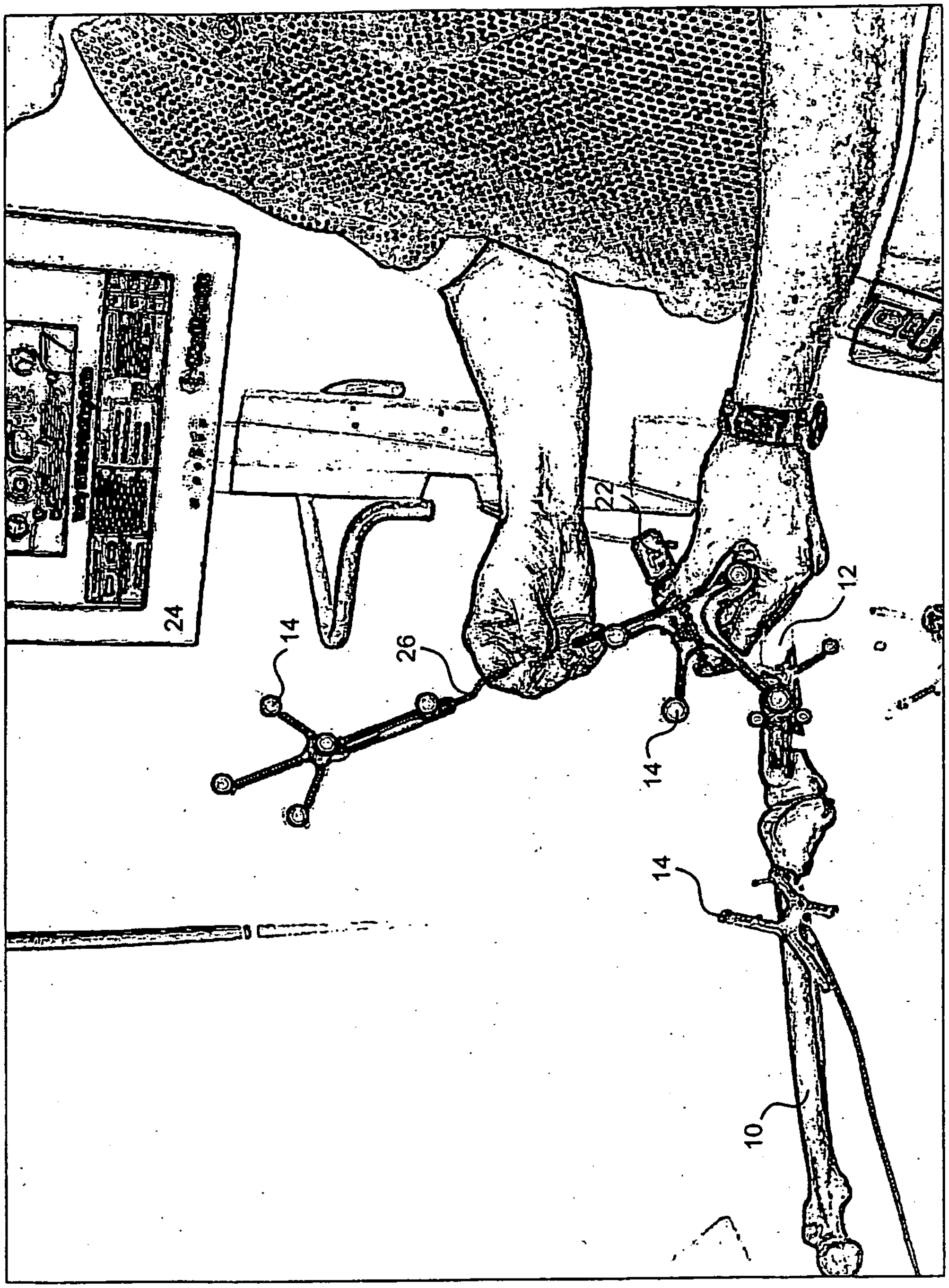


Fig. 11

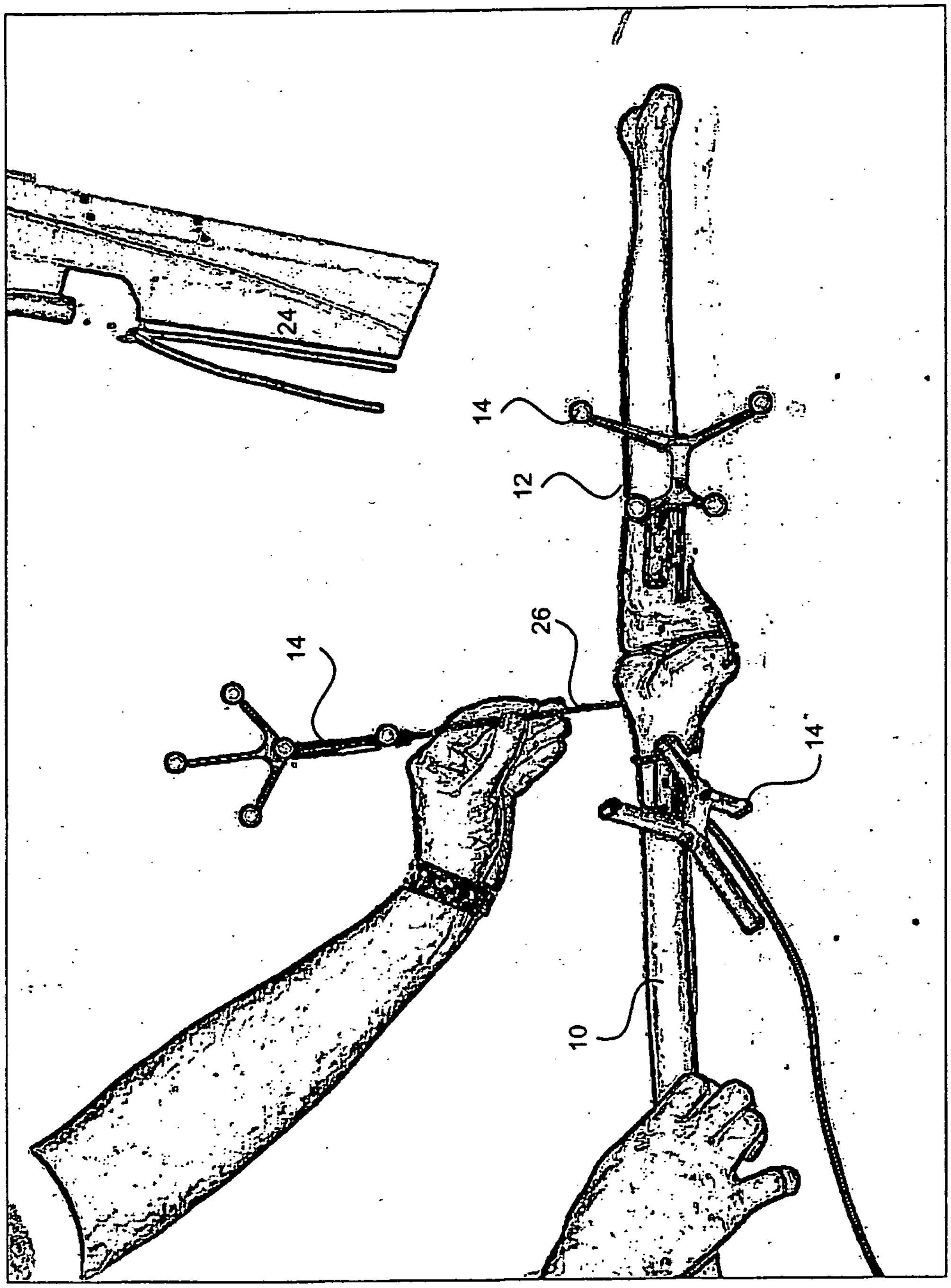


Fig. 12

Determine Femoral Mechanical Axis

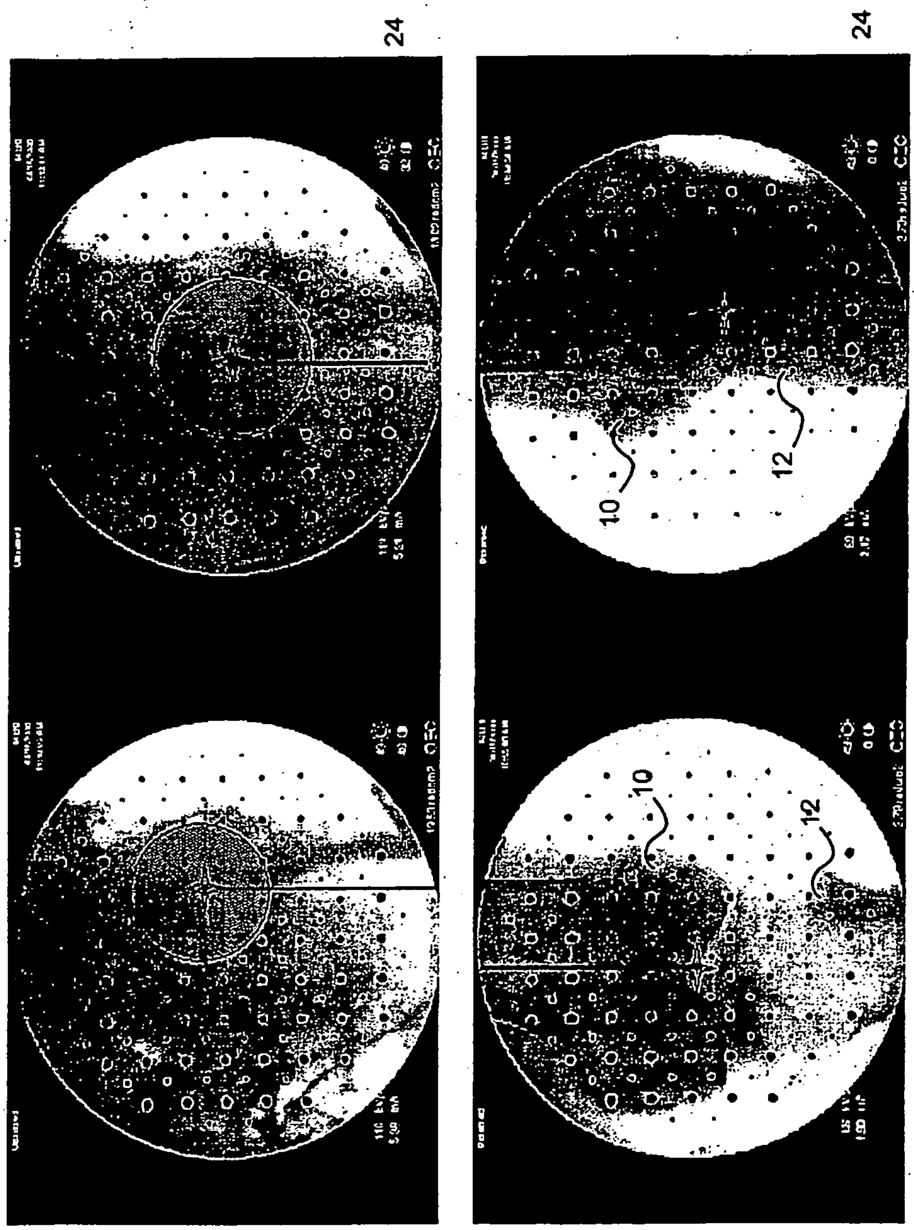


Fig. 13

Determine Epicondylar Axis

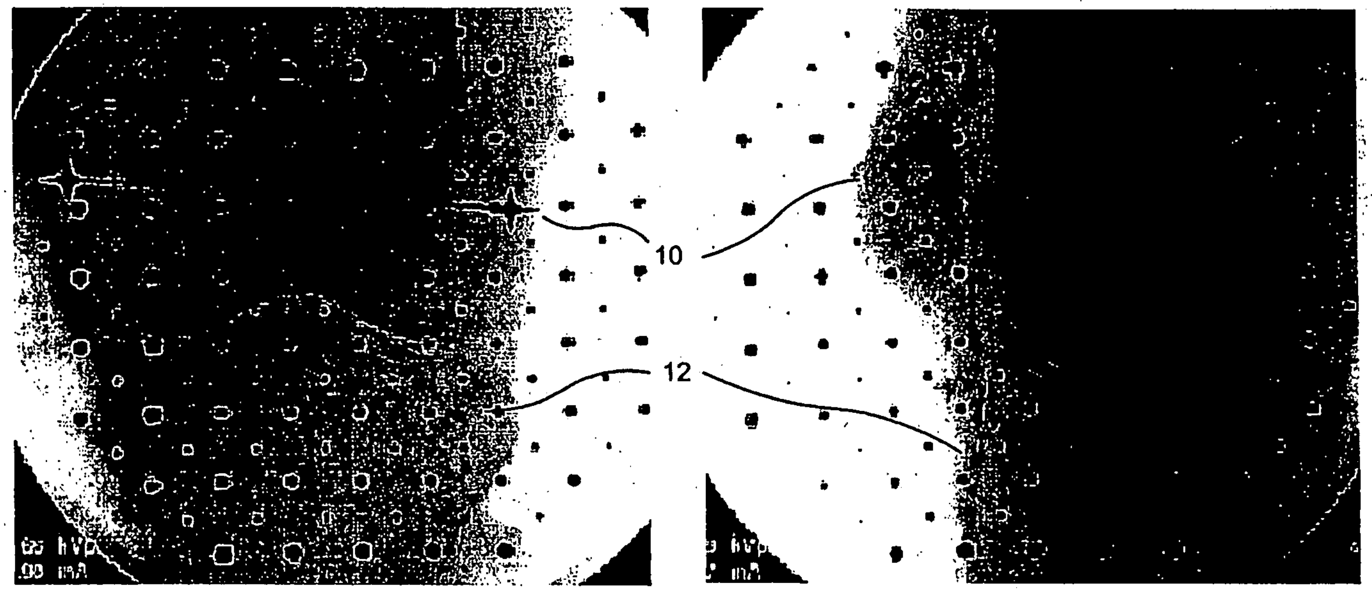


Fig. 14

Determine Anterior-Posterior Axis

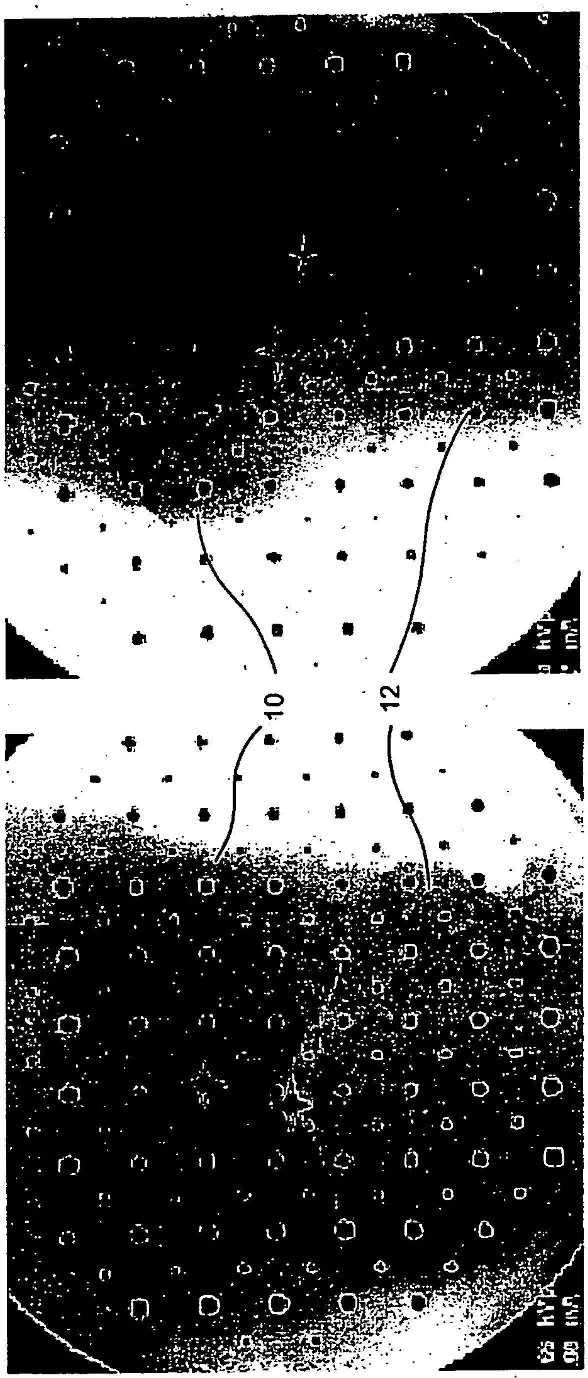


Fig. 15

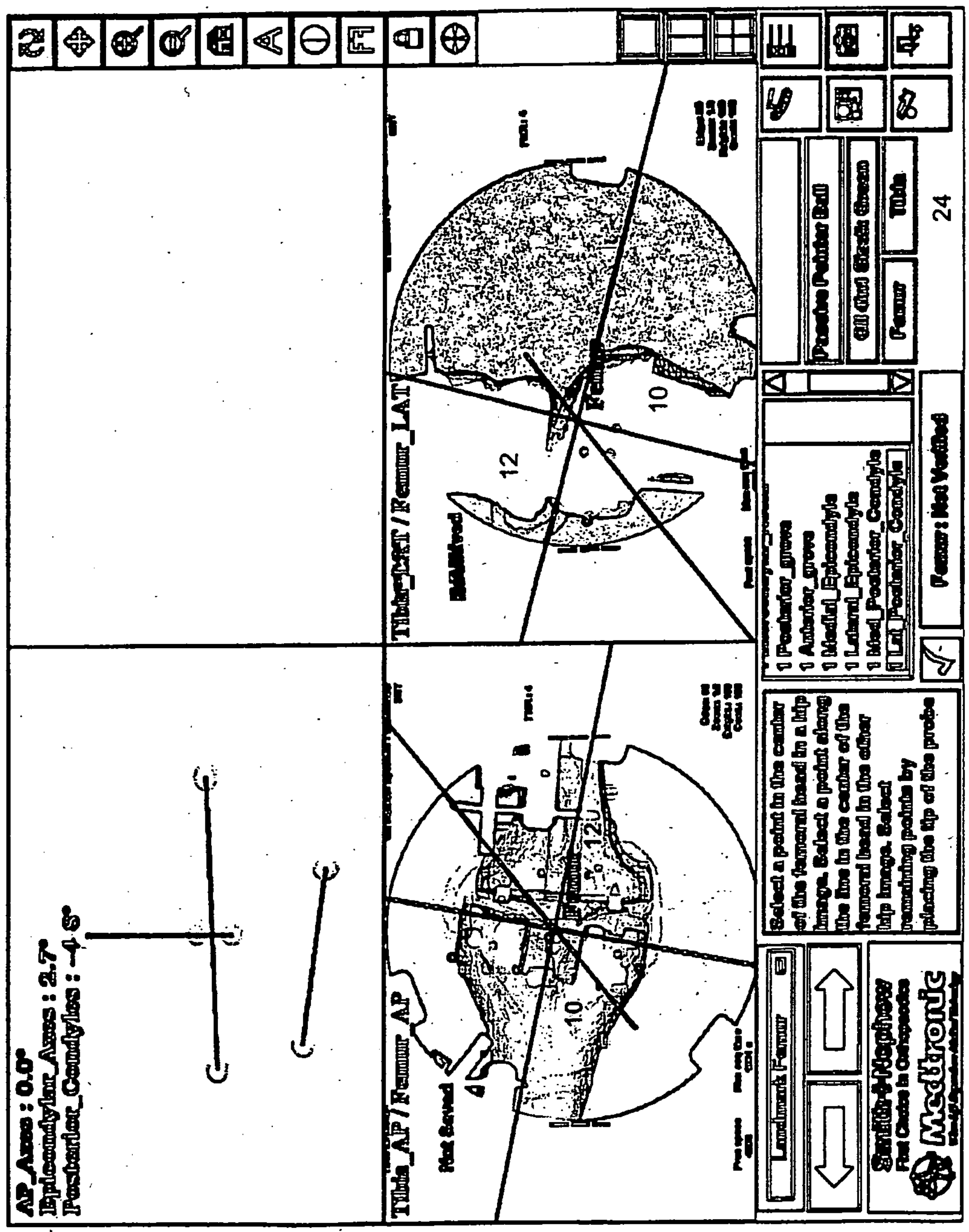

AP_Axes : 0.0°
Epicondylar_Axes : 2.7°
Posterior_Condyles : -4.5°
Tibia_AP / Femur_AP
Not Saved
10
12
Tibia_LAT / Femur_LAT
Landmark Femur
Select a point in the center of the femoral head in a hip image. Select a point along the line in the center of the femoral head in the other hip image. Select remaining points by placing the tip of the probe
1 Posterior_grove
1 Anterior_grove
1 Medial_Epicondyle
1 Lateral_Epicondyle
1 Med_Posterior_Condyle
1 Lat_Posterior_Condyle
Femur : Not Verified
Femur
Tibia
24
Medtronic

Fig. 16

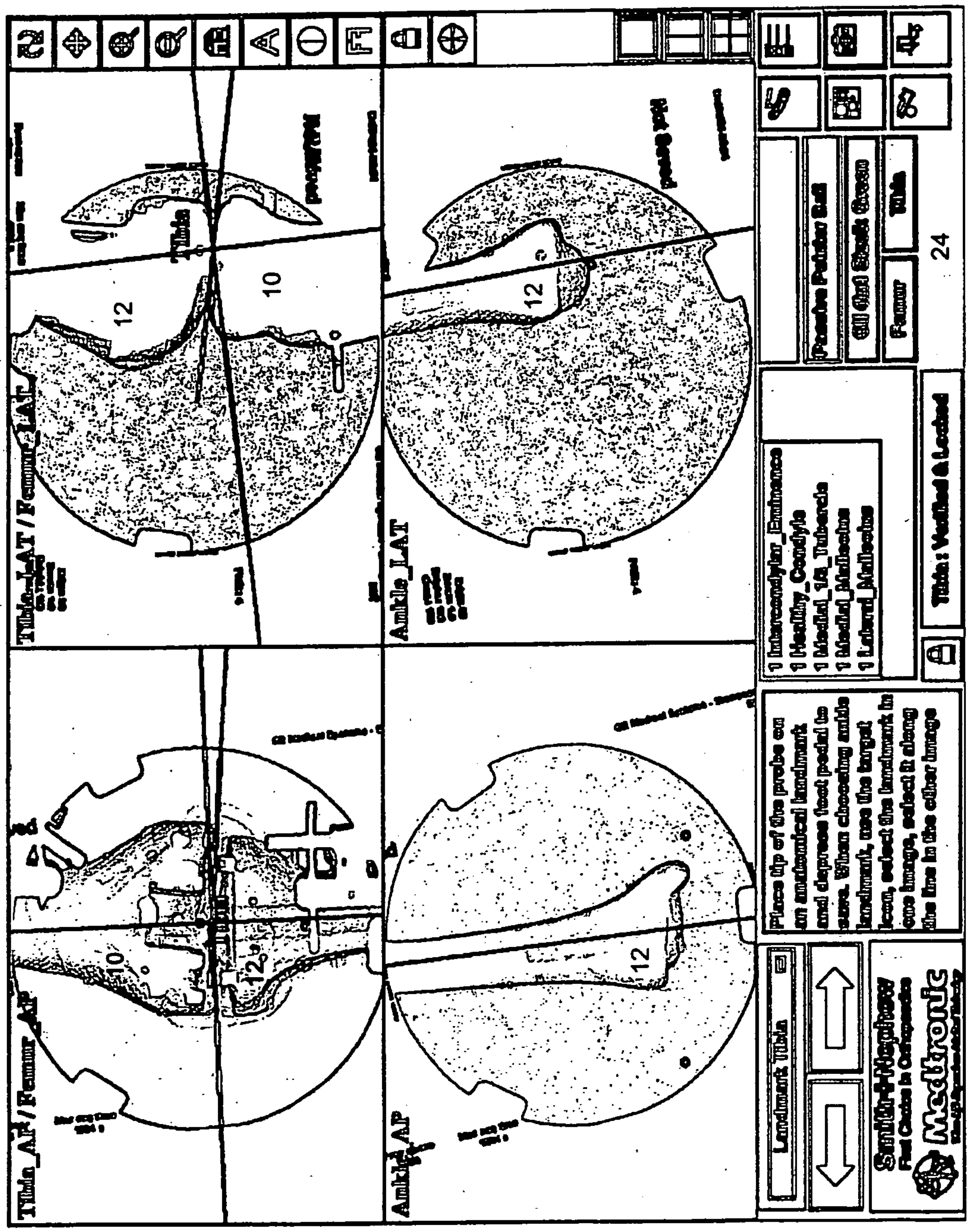

Tibia_AP / Femur_AP
Tibia_LAT / Femur_LAT
Ankle_AP
Ankle_LAT
12
10
24
Landmark Tibia
1 Intercondylar_Eminence
1 Healthy_Condyle
1 Medial_1/3_Tubercle
1 Medial_Malleolus
1 Lateral_Malleolus
Place tip of the probe on an anatomical landmark and depress foot pedal to save. When choosing ankle landmark, use the target icon, select the landmark in one image, select it along the line in the other image
Tibia : Verified & Locked
Femur
Tibia
Medtronic

Fig. 17

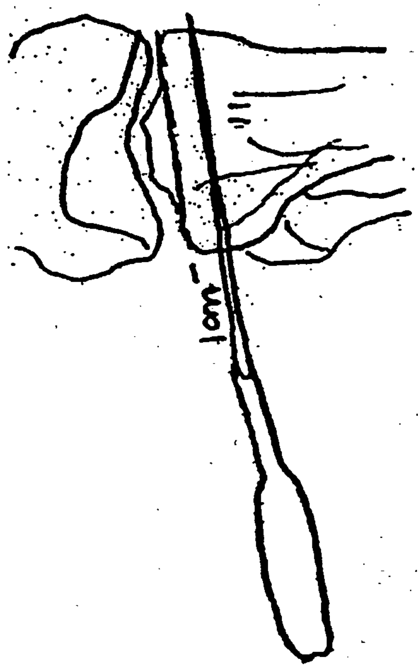


Fig. 18

Fig. 19

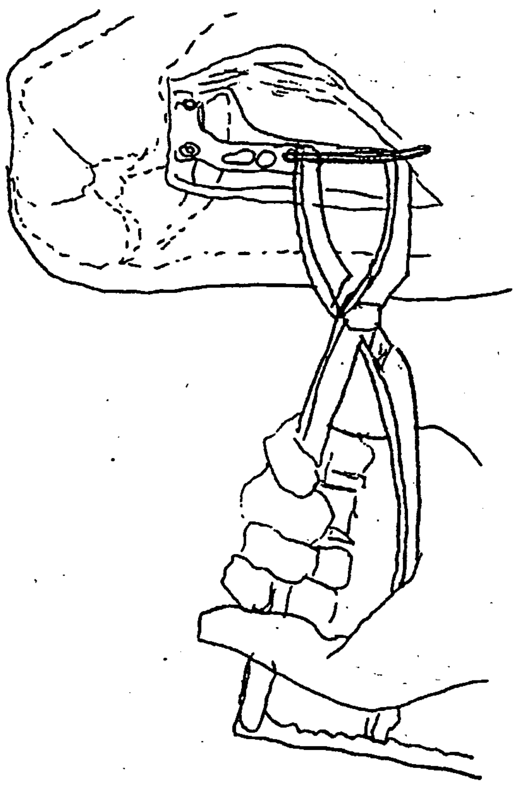


Fig. 20

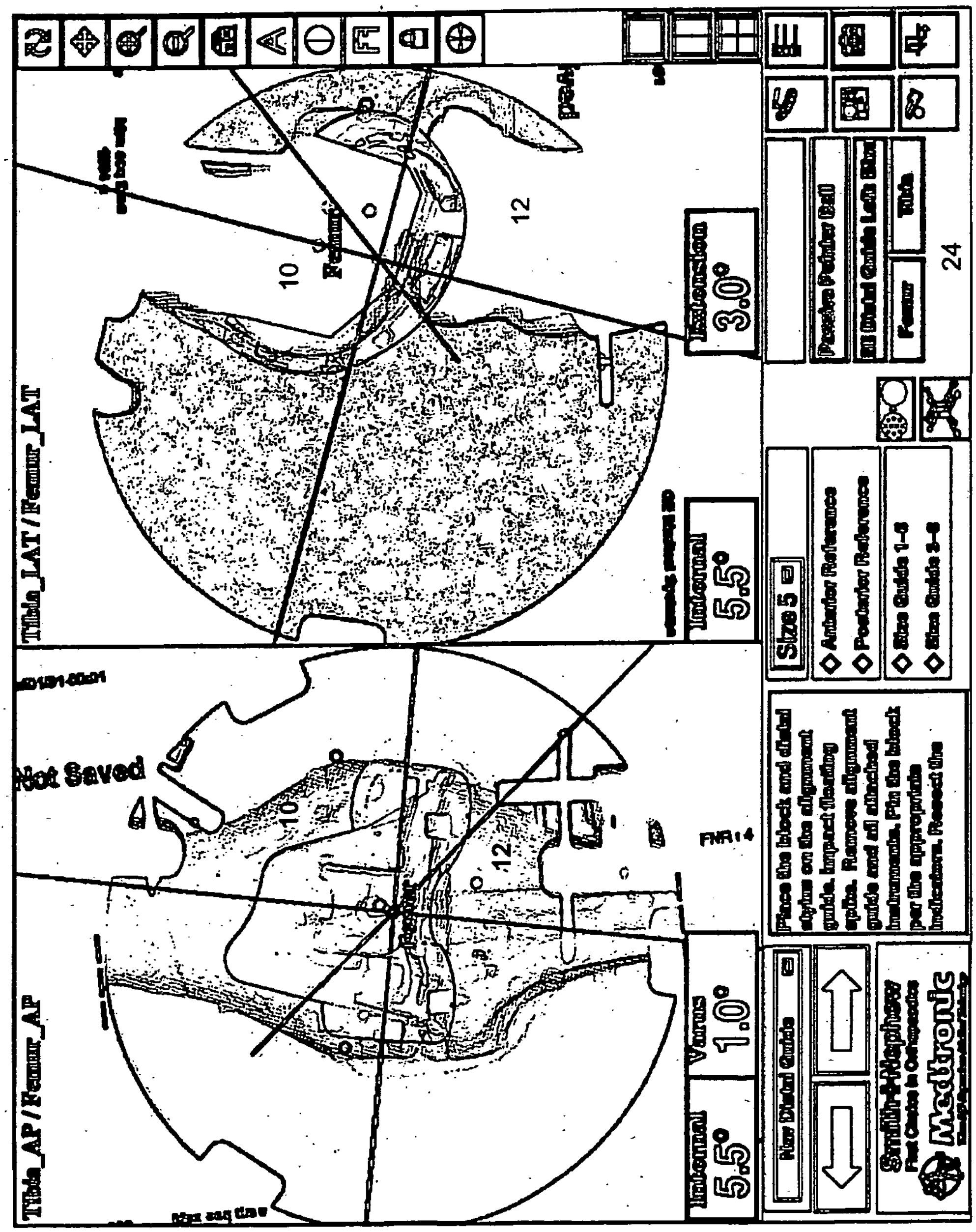

Tibia_AP / Femur_AP
Tibia_LAT / Femur_LAT
Not Saved
Internal
5.5°
Varus
1.0°
Internal
5.5°
Extension
3.0°
10
12
10
12
24
Size 5
Anterior Reference
Posterior Reference
Size Guide 1-5
Size Guide 3-8
Femur
Tibia
Smith & Nephew
Medtronic

Fig. 21

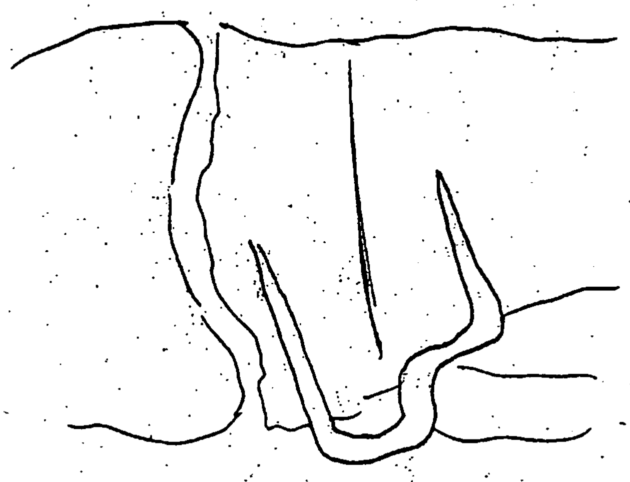


Fig. 22